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Evaluation of the Safety of the Situation (ESS) - Developing an EFCOG SAWG White Paper

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Evaluation of the Safety of the Situation (ESS)

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Outline

- Purpose of the ESS White Paper
- Background
- Purpose of an ESS
- Discussion Topics
 - What is an ESS?
 - Subtleties of an ESS
- ESS Outline
 - Several Options from the DOE Complex
- Consideration of Each Key Element of an ESS
- Timing of Submittal of an ESS
- Lessons Learned
 - Entry into PISA Process (and thus ESS)
 - ESS Relationship with Operability Determinations
- Conclusions
- Acknowledgments

Purpose of the ESS White Paper

- Concept of Evaluation of the Safety of the Situation (ESS) derives from a key step in the PISA process codified in 10CFR830.203.
- What constitutes ESS not well explained by Federal regulation or by DOE Order, Standard, or Guide.
- Variations have arisen regarding how to apply this concept.
- Share lessons learned and improve consistency, and at request of DOE HS-21 and DOE/NNSA contractor community.
 - Discuss official requirements/guidance from 10 CFR 830 and the DOE USQ Guide, DOE G 424.1-1A; best practices across the DOE Complex; lessons learned; details of implementation.

Background

- ESS “invented” when DOE O 5480.21 was translated into 10 CFR 830.
- PISA process, subset of USQ process of 10 CFR 830.203, must be entered when a contractor identifies or informed of situation that indicates safety analysis supporting DOE-approved safety basis may not be bounding or may be otherwise inadequate.
- In event of a PISA, 10 CFR 830.203 (g) requires the following actions:
 - Place or maintain the facility in a safe condition
 - Notify DOE of the situation
 - Perform a USQD and notify DOE promptly of the results
 - Submit the evaluation of the safety of the situation to DOE prior to removing any operating restrictions initiated as part of the first PISA action above
- 4th PISA action (ESS) is the mechanism for documenting information relevant to removal of operational restrictions.
- 3rd PISA action (USQD) influences the ESS.

Background

- Purpose of PISA USQD - determine if an actual inadequacy exists.
 - If PISA USQD Positive, Safety Basis is **Inadequate**.
 - Actual inadequacy of Safety Basis exists.
 - Situation involves a USQ and hence, according to 10 CFR 830.203(e), DOE approval of any subsequent actions is required.
 - Initiate a Justification for Continued Operations (JCO) and submit JCO to DOE for approval.
 - If PISA USQD Negative, Safety Basis is **Adequate**.
 - While situation may have been suspicious, an actual inadequacy does not exist.
 - Facility Manager can, without DOE approval, remove operational restrictions after submitting the ESS to DOE.
- Whether PISA USQD is Positive or Negative, an ESS must be submitted to DOE.

Purpose of ESS

DOE G 424.1-1A, B.14.3 PISA Requirement for ESS

- Terminology is in 10 CFR 830.203(g)(1) and (4), actions to taken in event of a PISA.
 - Demonstrates adequate safety with the existing situation so that interim measures (operational restrictions) to maintain facility in safe condition can be removed.
 - If that is not the case, then analysis should be accompanied by, or followed with, proposed resolution, also with safety analysis that demonstrates adequate safety.
 - No specific timing expectations for this step. Analyses take whatever time is required.
 - No specific format required,
 - Should be recognized that analyses can become part of safety basis, and should be done with appropriate degree of rigor.

Discussion Topics

- What is the ESS?
 - Facility Manager determines actual safety of proposed activity or discovered condition.
 - ESS is Facility Manager's qualitative assessment of relative risk of the situation and provides evidence to DOE for removal of controls.
- Role of the ESS different for a Positive or Negative USQD?
 - Negative USQD - ESS documents determination that necessary immediate controls placed on facility/activity to ensure safe conditions taken not required and can be removed.
 - Positive USQD - ESS may be a separate document or integral part of JCO and describes how actions outlined ensure safety.
- ESS should address and draw conclusion regarding adequacy of immediate safety actions (i.e., "operating restrictions").
 - Negative PISA USQD (Safety Basis **Adequate** – *no actual inadequacy*), ESS conclusion would most likely be operating restrictions sufficient.
 - Positive PISQ USQD (Safety Basis **Inadequate**), ESS conclusion might/might not be operating restrictions sufficient, especially to resolve all issues involved.

Discussion Topics

- Schedule
 - No specified schedule for submittal of ESS.
- DOE Approval
 - No requirement for DOE to approve ESS, unless it contains proposed corrective actions and PISA USQD is Positive.
- ESS Outline Variations
 - Several possible outlines
 - Variations around concept of Risk
 - Corrective Actions
 - Include planned corrective action into ESS
 - Provide planned corrective actions in separate subsequent document.
 - ESS separate or part of combined ESS/JCO
 - Lessons Learned
 - Initial/final ESS
 - Relationship of ESS with Operability Determination and JCO

ESS Outline – Option A

- **ESS may be letter from Contractor to DOE, or standalone document.**
- **ESS shall cover the following topics:**
 - Title
 - Description of occurrence or discovery and immediate compensatory actions taken.
 - Date PISA was discovered and ORPS report number.
 - Results of immediate safety assessment and of USQD (Positive/Negative).
 - Reference relevant documents.
 - Path forward.
 - Status of compensatory measures.
 - If appropriate, discuss if additional analysis to determine the cause of the PISA is being conducted, and anticipated completion date.
 - If appropriate, discuss if additional work is to be performed to resolve the issue, and anticipated completion date.
 - If a JCO is necessary, prepare and submit JCO for approval.

ESS Outline – Option B

- **Similar to Option A, but splits ESS based on whether PISA USQD is Positive or Negative.**
- An ESS for a situation where a PISA USQD:
 - **Negative**, ESS documents the Facility Manager's qualitative assessment of the relative risk of the situation and provides evidence that the immediate controls placed on the facility or activity to ensure safe conditions are not required and can be removed.
 - **Positive**, ESS documents the Facility Manager's qualitative assessment of the relative risk of the situation, and provides the basis for how the actions outlined ensure safety.
 - ESS may be standalone document or integral part of JCO.
 - Efficiencies may be achieved by consolidating ESS and JCO as long as "ESS" clearly indicated in title when combined JCO/ESS transmitted to DOE.

ESS Outline – Option C

- **ESS may be letter from Contractor to DOE, or a standalone document.**
- **ESS shall cover the following topics:**
 - Title [short, descriptive]
 - Description of occurrence or discovery.
 - Date PISA was confirmed and ORPS report number.
 - Description of the immediate compensatory actions taken (that is, operating restrictions).
 - Results of the PISA USQD (Positive/Negative).
 - Reference relevant documents, but submittal in general is not required.
 - Risk assessment that addresses the risks associated with the discovered conditions with the operating restrictions in effect. Current status of the operating restrictions (e.g. still in effect).
 - Identify and summarize any JCO(s) related to the discovered PISA conditions.
 - Path forward
 - Status of compensatory measures.
 - If appropriate, discuss if additional analysis to determine the cause of the PISA is being conducted, and anticipated completion date.
 - Describe any corrective actions that have already been formulated or provide an estimated target date for the submittal of the corrective actions plan.
 - If corrective actions already formulated and included in ESS, explanation of adequacy of those planned actions should also be included.
 - If JCO necessary, prepare and submit JCO for approval (see DOE G 424.1-1A).
- **Question: Should JCO be prepared before ESS is completed?**
 - If so, then it is mentioned in the ESS only in passing for sake of completeness.

ESS Outline – Option D

- **ESS is qualitative discussion on why it is safe to remove the operational restrictions that were put in place as a result of a PISA.**
 - Demonstrates that the risk DOE has accepted not increased or provides a safety basis change for DOE approval.
 - Identifies the protection that operational restrictions provided, and evidence that potential increased risk is not a valid concern.
- **A suggested content of the ESS includes:**
 - Summary of PISA determination,
 - Listing of interim operational restrictions and their purposes,
 - Results of USQD (Positive/Negative).
 - Description of review actions taken,
 - Conclusion of safety review, and
 - Statement of disposition of operational restrictions

ESS Outline – Option E

- **ESS is qualitative, management-level assessment of safety implications of condition and effectiveness of initial actions implemented in response to PISA.**
 - NOT include corrective measures associated with USQ or path forward.
- **To evaluate safety of situation, determine if facility in safe condition. Appropriate steps to do this include:**
 - Hazard Identification
 - Controls
- **ESS as part of USQ transmittal letter or submitted separately.**

Consideration of Each Key Element – Option A

- **Title**
 - Short, descriptive title
- **Description of occurrence or discovery and immediate compensatory actions taken.**
 - State what is the PISA.
 - Example - “This letter [or standalone document] provides the Evaluation of the Safety of the Situation involving [short descriptive title].”
- **Date PISA was discovered and ORPS report number.**
 - ORPS report number facilitates communication between Contractor, DOE, and others, while minimizing potential confusion when multiple PISAs may exist for same organization.
 - Example - “A PISA for [facility/operation] was discovered on [date]. *[Describe the discovery/new information/occurrence. Use ORPS report for information. Keep it brief. Refer to ORPS report by number.]* This information is being supplied to DOE in compliance with 10 CFR 830.203(g).”

Consideration of Each Key Element – Option A

- **Results of immediate safety assessment and of USQD (Positive/Negative).**
 - Example – fire analysis, analytical results
 - Reference relevant documents (e.g., the USQD #).
- **This element provides relationship between ESS and USQD.**
 - ESS states whether USQD was Positive or Negative.
 - In doing so, ESS conveying whether issue within or outside the Safety Basis, and thus whether contractor or DOE approval required.
 - This in turn determines subsequent steps for removing operational restrictions.
 - Negative USQD - Facility Manager can remove operational restrictions after submitting ESS to DOE.
 - Positive USQD - DOE approval required to remove operational restrictions. That approval requires submittal of ESS.
- **Example** - “An immediate assessment of the impact of the [*discovery/new information/occurrence*] on the safety of the facility was completed [*reference any completed documents*] and a USQD was performed to determine possible impacts to the DOE-approved safety basis. The USQD was [*Positive/Negative*] based on [*for Positive only – briefly discuss questions that were positive and implications to safety basis.*]”

Consideration of Each Key Element – Option A

- **Path forward**
 - Status of compensatory measures.
 - If appropriate, discuss if additional analysis to determine cause of PISA being conducted, anticipated completion date.
 - **Example** - “Additional analysis to determine the cause of the [event/situation/discovery] is currently being conducted, and should be completed no later than [date]. Until this evaluation is complete and any necessary changes to the facility and its operations have been evaluated, *[discuss as necessary.]* Any significant additional information developed during this evaluation will be communicated in an update to the ORPS report.” *[Closing paragraph]*
 - If appropriate, discuss if additional work is to be performed to resolve the issue, and anticipated completion date.
 - If JCO is necessary, prepare and submit JCO for approval.
- **Status of compensatory measures**

Consideration of Each Key Element – Options C, D, and E

- **Combined ESS/JCO**
 - Considerations:
 - Timeliness
 - Risks with auditors in combined document meeting expectations for both ESS and JCO
- **Description of immediate compensatory actions taken/ operating restrictions**
 - Is this description necessary for a ESS where PISA USQD that is Negative and operating restrictions can be lifted without DOE approval?
- **Risk assessment**
 - Risk assessment addresses risks associated with discovered condition(s) with operating restrictions *in effect*.
 - Current status of operating restrictions (e.g. *operating restrictions still in effect*).
 - What is the purpose of the ESS?
 - Facility Manager determines actual safety of proposed activity or discovered condition.
 - ESS is Facility Manager's qualitative assessment of relative risk of the situation and provides evidence to DOE for removal of controls.

Consideration of Each Key Element – Options C, D, and E

- **Steps to determine if facility is in safe condition – how much documentation is required?**
 - Hazard Identification
 - Event that occurred
 - Existing/current condition of facility
 - Hazards introduced by event
 - Hazards associated with existing/current condition of facility
 - Controls
 - Defining controls that needed as result of event and existing/current condition of facility
 - Determine if previously approved controls sufficient
 - Determine if new controls required
- **Again, what is the purpose of the ESS?**

Timing of Submittal of an ESS

- **No specified schedule for submittal of ESS.**
 - 10CFR830 requires contractors submit ESS prior to removing operational restrictions.
- **DOE G 424.1-1A states,**
 - No specific timing expectations for this step.
 - Analyses take whatever time required.
 - No specific format required, but it should be recognized that analyses can become part of safety basis, should be done with appropriate degree of rigor.
- **Lessons learned revealed confusion in details of implementation.**
 - Specifically cases where operational restrictions not removed in near term,
 - Analyses may take time, proportional to degree of rigor expected by DOE.
 - Operational restrictions required to left in place for considerable periods (e.g., funding must be obtained to fix problem which resulted in PISA).
 - External Organizations, Auditors, and some DOE Site Offices expect contractors to submit ESS promptly, not just prior to removal of operational restrictions.
 - Concept of initial/final ESS emerged
 - Submit initial ESS with compensatory measures in place
 - Conduct analysis (e.g., Operability Determination)
 - Submit final ESS once analysis complete or problem fixed
 - However, initial/final ESS concept overlaps with JCO
 - Role of JCO in obtaining DOE approval to continue
 - No need for final ESS therefore no need for initial/final ESS concept

Timing of Submittal of an ESS – DOE/Contractor Oversight

- **Timing of submittal of ESS may be a function of the DOE/Contractor Oversight.**
- **Importance of developing/maintaining good working relationship.**
- **Situation A.** DOE Facility Representative Program, Cognizant System Engineer (CSE) Program, and Safety System Oversight (SSO) Program well developed, and very good working relationship developed between contractor and DOE.
 - ESS reflects what has been verbally agreed upon amongst parties involved.
 - ESS is in effect formalization of agreed-upon positions -> DOE approvals processed smoothly and promptly.
- **Situation B.** Working relationship between contractor and DOE not so well developed, ESS may take on an *additional role that may be better handled separately*.
 - ESS may not be fully discussed before submittal
 - DOE approval of ESS may be more involved and less timely.
- **Consider - Is the information new to DOE?**
 - Should you assume that the information presented in ESS, JCO, and Operability Determination being presented to DOE for the first time?
 - Situation A – No; DOE Fac Rep, CSE, SSO aware of what is going on for areas of their responsibility.
 - Situation B – Yes?
 - Outside of ESS process, appropriate DOE personnel should be quickly informed of discovery of PISA and frequently kept up to date regarding development of ESS, JCO, and Operability Determination.

Lessons Learned – Entry into PISA Process (and thus ESS) should not be judged as inappropriate contractor performance

- DOE-HQ has traditionally highlighted that DOE Site Offices should not provide disincentives for contractors to follow the PISA process
- PISA process is simply a defined mechanism for dispositioning issues that require DOE involvement.
- Entry into the process should not be construed as a judgment of inappropriate contractor performance.
- It is failure to properly utilize the process that may reflect on performance. It is noted that PISA refers to a “potential” inadequacy.
- Remember, “P in PISA”.
 - *Potential* inadequacy
- Awareness: Contractor and DOE Contract officials may not be aware of this when writing a Contract’s Performance Based Incentives (PBIs)

Lessons Learned – ESS Relationship with Operability Determinations

- Relationship of ESS with JCO is discussed in DOE G 424.1-1A and the EFCOG JCO white paper.
- Relationship with Operability Determination is less clearly established.
- Sometimes appropriate, prepare Operability Determination support ESS.
 - Discrepant as-found condition is a situation where the actual physical configuration in facility does not match DSA. This may result from error in DSA or error in facility configuration.
 - Leaving SSC in degraded state (i.e., use-as-is) does invoke PISA considerations under discrepant as-found condition.
- Questions
 - What triggers the need for an Operability Determination?
 - How do you address it in the ESS? Example – “See attached Operability Determination”
- **Path forward**
 - ESS with Operability Determination
 - ESS with JCO
 - ESS with both Operability Determination and JCO – inappropriate?

Lessons Learned – ESS Relationship with Operability Determinations (EFCOG JCO white paper)

- **Some confusion between Operability Determination and JCO.**
- **Essence of Operability Determination - when SSC becomes degraded, ascertain if SSC able to perform its safety functions and meet associated functional requirements and performance criteria.**
- **Operability Determination uses principles of DOE G 423.1-1, TSR Implementation Guide.**
 - If SSC can perform its safety function etc., SSC remains operable.
 - Example - not unusual for some nuclear instrumentation channels important to safety to provide panel-mounted indicator as well as strip-chart recorder. If recorder were not functioning, safety function of instrumentation channel might still be met.
- **Operability Determination determines if degraded SSC operable in meeting its safety needs, albeit not able to meet some other needs.**
- **If SSC remains operable, facility TSRs continue to be satisfied, and facility operations may continue.**
- **JCO for situation where SSC not operable, but there is safety rationale for not having to cease operations.**

Conclusions

- **Concept of ESS derives from key step in PISA process codified in 10CFR830.**
- **Mechanism for documenting information relevant to removal of operational restrictions.**
- **Address and draw conclusion regarding adequacy of immediate safety actions (i.e., “operating restrictions”).**
 - Negative PISA USQD (Safety Basis **Adequate** – *no actual inadequacy*), ESS conclusion would most likely be operating restrictions sufficient.
 - Positive PISA USQD (Safety Basis **Inadequate**), ESS conclusion might/might not be operating restrictions sufficient, especially to resolve all issues involved.
- **EFCOG SAWG USQ Subgroup has therefore reached the following conclusions:**
 - Consistent approach on topics outlined in this presentation will help address variations in ESS across the DOE Complex.
 - Final version of ESS white paper will provide guidance on: outline for ESS, how outline is different for Positive/Negative USQD, discussion of how to consider each key element of ESS, timing of submittal of ESS, triggering Operability Determination, and relationship of ESS with Operability Determination.

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DOE G 424.1-1A

B.14.3 PISA Requirement for an Evaluation of the Safety of the Situation

- USQ requirements relating to PISAs include that in event of PISA, and after formal USQD, ESS be performed and results submitted to DOE prior to removing any operational restrictions taken to maintain facility in safe condition.
- Terminology is in 10 CFR 830.203(g)(1) and (4), and refers to actions to be taken in event of a PISA.
 - Basically, a safety evaluation is a safety analysis that demonstrates adequate safety with the existing situation so that any interim measures (operational restrictions) to maintain the facility in a safe condition can be removed. If that is not the case (adequate safety), then the analysis should be accompanied by, or followed with, a proposed resolution, also with a safety analysis that demonstrates adequate safety.
- No specific timing expectations for this step. Analyses take whatever time is required.
- No specific format required, but it should be recognized that analyses can become part of safety basis, and should be done with appropriate degree of rigor.
- If PISA USQD (see 10 CFR 830.203(g)(3)) is negative, then ESS submitted to DOE prior to removing operational restrictions,
 - Explicit DOE approval not required, as with any negative USQD. DOE may, however, not agree with analysis or think it is not adequate, in which case DOE may require further steps.
- If USQD is positive, then DOE approval is required for any proposed resolution, including interim restrictions. Often this is also the situation that a JCO is prepared.

Lessons Learned – ESS Relationship with Operability Determinations (DOE G 424.1-1A)

- **Necessary to determine the proper handling of situations expeditiously under the USQ requirements where it is found that SSC does not conform to safety basis description and requirements (discrepant as-found state).**
 - **SSC may be degraded such that there is loss of quality or functional capability or nonconforming condition may exist with SSC or its documentation.**
- **When degraded or nonconforming SSC is identified as PISA, contractor must first “take action, as appropriate, to place or maintain the facility in a safe condition” (10 CFR 830.203(g)(1)).**
 - **Safe condition may include continued facility operation if, although degraded or nonconforming SSC not fully qualified, impact on safe facility operations judged to be acceptable, possibly aided by operational restrictions.**
 - **Operability Determination is forward-looking evaluation by contractor of whether there is reasonable expectation that continued operation of facility is safe even when degraded or nonconforming condition (PISA) and USQ exists.**
 - **Immediate operability determination should be made based on best available information and operational restrictions imposed, if necessary, upon confirmation of condition.**
 - **Subsequently, final determination should be made and documented following thorough engineering evaluation. Elements of final operability determination should include:**
 - description of degraded or nonconforming condition of SSC
 - description of relationships on safe operations of SSC functions
 - evaluation of operability of SSC given its condition—
 - using analysis, tests, operating experience, and/or engineering judgment
 - considering availability of other equipment, conservatisms and margins, and cumulative effects of other outstanding degraded or nonconforming conditions
 - specification of additional operating restrictions if necessary (e.g., compensatory measures, additional engineering analysis by a certain date)
 - specification of restoration actions (may be added later).
 - **Restoration actions for degraded or nonconforming condition to be developed by contractor and scheduled at first available opportunity commensurate with DOE G 424.1-1A safety significance and extent of restoration actions in an integrated manner with other facility commitments and resources.**
 - **Final operability determination may be included as part of ESS required to be submitted to DOE before removal of any operational restrictions.**